DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2015

AEROCRINE AB
KATHLEEN RICKARD
CHIEF MEDICAL OFFICER
RASUNDAVAGEN 18, 8TH FLOOR
SOLNA SE-169 67 SE

Re: K150233
Trade/Device Name: NIOX® VERO Airway Inflammation Monitor
Regulation Number: 21 CFR 862.3080
Regulation Name: Breath nitric oxide test system
Regulatory Class: II
Product Code: MXA
Dated: January 30, 2015
Received: February 2, 2015

Dear Ms. Rickard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -A

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150233

Device Name
NIOX® VERO Airway Inflammation Monitor

Indications for Use *(Describe)*
NIOX VERO® measures Nitric Oxide (NO) in human breath. Nitric Oxide is frequently increased in some inflammatory processes such as asthma. The fractional NO concentration in expired breath (FeNO), can be measured by NIOX VERO according to guidelines for NO measurement established by the American Thoracic Society.

Measurement of FeNO by NIOX VERO is a quantitative, non-invasive, simple and safe method to measure the decrease in FeNO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy, as an indication of the therapeutic effect in patients with elevated FeNO levels. NIOX VERO is suitable for children, approximately 7 - 17 years, and adults 18 years and older.

FeNO measurements provide the physician with means of evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to the established clinical and laboratory assessments in asthma. The NIOX VERO is intended for prescription use and should only be used as directed in the NIOX VERO User Manual by trained healthcare professionals. NIOX VERO cannot be used with infants or by children approximately under the age of 7, as measurement requires patient cooperation. NIOX VERO should not be used in critical care, emergency care or in anesthesiology. VERO User Manual by trained healthcare professionals. NIOX VERO should not be used in critical care, emergency care or in anesthesiology.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Aerocrine

NIOX® | CHANGING THE FACE OF ASTHMA CONTROL

SPECIAL 510(k) SUMMARY

The assigned 510(k) number is: K150233

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR 807.92.

Preparation Date: February 24, 2015

510(k) Applicant:
Aerocrine AB
Råsundavägen 18, 8th Floor
SE-171-21 Solna, Sweden
Phone: +46-8-629-0780
Fax: +46-8-629-0781

Contact Person:
Susanne Parks
Global Director Regulatory Affairs & Quality Assurance

Trade Name: NIOX VERO®

Common Name: Airway Inflammation Monitor

Classification Name: System, Test, Breath Nitric Oxide
Regulatory Class: Class II
Product Code: MXA
CFR Section: 21 CFR 862.3080

Predicate Device: NIOX VERO® Airway Inflammation Monitor
510(k) Clearance Number: K133898
Class II under 21 CFR 862.3080, Product Code MXA

510(k) Applicant:
Aerocrine AB
Råsundavägen 18, 8th Floor
SE-171-21 Solna, Sweden
Phone: +46-8-629-0780
Fax: +46-8-629-0781

Device Description

NIOX VERO is a portable system for the non-invasive, quantitative measurement of the fraction of exhaled nitric oxide (NO) in expired human breath (FeNO). NO levels increase during allergic airway inflammation. Measurement of changes in FeNO concentration is used in evaluating a patient's response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments.

The NIOX VERO system is comprised of the NIOX VERO unit with AC adapter, a rechargeable battery, an electrochemical NO sensor, disposable patient filters, and an exchangeable handle containing an internal NO scrubber filter. The NIOX Panel is an optional PC application for operation of the NIOX VERO from a PC and access to electronic medical record systems. The device can connect to the PC via a standard USB cable or wirelessly via Bluetooth.

The patient empties their lungs, inhales deeply through the patient filter to total lung capacity and then slowly exhale for 10 seconds. In approximately one minute, the NO concentration is displayed in parts per billion (ppb).

The NIOX VERO unit includes a sampling and gas conditioning system and a man-machine interface (MMI). The instrument controls the inhaled sample appropriately via the electronics and software program. Filtering of inhaled air eliminates contamination from ambient NO levels. A built-in flow control keeps exhalation standardized at 50 ml/s so that it is standardized for all patients. The sample enters an electromechanical sensor and interacts with an electrolyte. A chemical reaction takes place where electrons are generated proportional to the number of NO molecules.

Results are processed using dedicated software. In order to verify the device's performance and reliability of measurements, there are built-in system control procedures and a Quality Control procedure to be performed on a daily basis.

Intended Use/Indications for Use

NIOX VERO® measures Nitric Oxide (NO) in human breath. Nitric Oxide is frequently increased in some inflammatory processes such as asthma. The fractional NO concentration in expired breath (FeNO), can be measured by NIOX VERO according to guidelines for NO measurement established by the American Thoracic Society.

Measurement of FeNO by NIOX VERO is a quantitative, non-invasive, simple and safe method to measure the decrease in FeNO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy, as an indication of the therapeutic effect in patients with elevated FeNO levels. NIOX VERO is suitable for children, approximately 7 - 17 years, and adults 18 years and older.

FeNO measurements provide the physician with means of evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to the established clinical and laboratory assessments in asthma. The NIOX VERO is intended for prescription use and should only be used as directed in the NIOX VERO User Manual by trained healthcare professionals. NIOX VERO cannot be used with infants or by children approximately under the age of 7, as measurement requires patient cooperation. NIOX VERO should not be used in critical care, emergency care or in anesthesiology. VERO User Manual by trained healthcare professionals. NIOX VERO should not be used in critical care, emergency care or in anesthesiology.

Technological Characteristics Compared to Predicate

Trade Name	NIOX VERO®	NIOX VERO®
510(k) Number	K150233	K133898
Regulatory Class	Class II	Class II
Regulation Number	21 CFR 862.3080	21 CFR 862.3080
Product Code	MXA	MXA
Intended Use	Identical	See above
Analytical limits at low levels, (limit of detection)	Identical to predicate	5 ppb
Precision	Identical to predicate	< 3 ppb of measured value for values < 30 ppb < 10% of measured value for values ≥30 ppb
Accuracy	Identical to predicate	+/- 5 ppb or max 10%
Measurement Range	Identical to predicate	5 - 300 ppb
Linearity, reportable range	Identical to predicate	Squared correlation coefficient $r^2 \geq 0.998$, slope 0.95 – 1.05, intercept ±3ppb
PC Connection	Bluetooth wireless and USB	USB

The scope of this 510(k) application is the activation of existing Bluetooth technology on the predicate device. The Bluetooth module was present in the previously cleared device, but not active. The activation of the module functionality does not impact the existing device measuring functionality or specifications as it acts as a wireless serial connection only and as an alternate to direct connection via USB cable. As shown above the subject device is identical to the predicate except for Bluetooth operation.

The NIOX VERO software and firmware cleared as part of K133898 already contains the Bluetooth functionality and no software or firmware alterations were necessary to implement this change. The factory configuration for US based NIOX VERO products has been altered to implement this change

Performance Testing

The Bluetooth functionality for the NIOX VERO is currently available outside the US market. Verification and validation testing was previously performed for Bluetooth functionality prior to FDA clearance. The activation of Bluetooth for the US market did not require additional verification and validation of the hardware or software since the testing was previously completed and there were no changes in the hardware or software as part of the update to the device.

Risk analysis documentation has been updated to include additional risks from wireless operation. Wireless coexistence testing has been performed to verify that there are no risks present from wireless interference in the clinical setting. FCC Part 15B testing was repeated with the Bluetooth module active in the NIOX VERO.

This testing was performed as per the FDA Radio Frequency Wireless Technology in Medical Devices issued on 13 August 2013. The results of this testing can be found in the body of this Special 510(k) application and demonstrate that Bluetooth operation in the NIOX VERO device does not create additional risks from wireless interference in the intended device use setting.

Conclusions:

The updated NIOX VERO has the same intended use as the predicate device. The device modifications do not affect the device's fundamental scientific technology, clinical performance, hardware or software as the functionality was previously implemented in the predicate, but not active in the US market

Wireless coexistence testing and risk analyses have demonstrated that any risks from interference have been properly mitigated as necessary to ensure wireless compliance and safety in the NIOX VERO's intended use environment. Verification and validation were previously performed to demonstrate that the USB cable communications functions are equivalent to the Bluetooth wireless communication operation.

The activation of existing Bluetooth functionality coupled with the appropriate wireless coexistence and FCC testing as per the FDA Guidance and previous verification and validation testing demonstrate that the subject device is as safe and effective as the predicate.